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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,403	07/08/2003	Joe W. Gray	023070-139300US	9224
20350 7590 08/13/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 08/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/616,403

Applicant(s)

GRAY ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 7-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/13/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-6 and 15, SEQ ID NO: 2) in the reply filed on December 18, 2006 is acknowledged. The traversal is on the ground(s) that "...the subject matter of elected Group I would likely encompass the subject matter of Groups IV, VII, X and XIII" and hence the "...groups could be searched together without undue burden". This is not found persuasive because Groups IV, VII, X and XIII read on different and distinct methods that are not useable and searchable together as indicated in the Requirement mailed June 1, 2006.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-15 are pending.

Claim 1 has been amended.

Claims 7-14, drawn to non-elected inventions are withdrawn from examination.

Claims 1-6 and 15 are examined on merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1-6 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 6,372,444 (issued April 16, 2002), as evidenced by Jiang et al. (Science 283: 543-546, 1999/ IDS reference A3 submitted October 13, 2005). The patent discloses methods for diagnosing breast cancer by detecting suppressor of death domain (SODD) polynucleotides in a tissue biopsy wherein an elevated level of SODD opposed to a normal/control sample detects presence of cancer cells, see column 3, lines 27-54; column 8, lines 20-67; column 9, lines 40-45; column 18, lines 32-37; and the claims of columns 19 and 20. The SODD molecules are evidenced by Jiang and are the same as Applicants' SEQ ID NO: 2, see column 2, lines 7-15; attached rup database sheets; Jiang, page 544, Figure 1A and caption, wherein GenBank accession number AF111116 is cited; and Applicants' specification, page 5, section 0025. The disclosed molecules are identified as SODD molecules, otherwise known as BAG4 molecules or silencer of death domains, see specification, page 4, section 0022, lines 15 and 16. The detection step may involve amplification-based assays and detecting

gene copy number, see column 4, lines 12-22; and column 5, lines 56-62. The disclosed method is implemented in conjunction with one or more traditional and well known anti-cancer therapies, see column 9, line 57-column 10, line 4; and column 10, lines 25-37.

5. Claims 1-6 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,372,444 (issued April 16, 2002), as evidenced by Jiang et al. (Science 283: 543-546, 1999/ IDS reference A3 submitted October 13, 2005). The patent discloses methods for diagnosing breast cancer by detecting suppressor of death domain (SODD) polynucleotides in a tissue biopsy wherein an elevated level of SODD opposed to a normal/control sample detects presence of cancer cells, see column 3, lines 27-54; column 8, lines 20-67; column 9, lines 40-45; column 18, lines 32-37; and the claims of columns 19 and 20. The SODD molecules are evidenced by Jiang and are the same as Applicants' SEQ ID NO: 2, see column 2, lines 7-15; attached rup database sheets; Jiang, page 544, Figure 1A and caption, wherein GenBank accession number AF111116 is cited; and Applicants' specification, page 5, section 0025. The disclosed molecules are identified as SODD molecules, otherwise known as BAG4 molecules or silencer of death domains, see specification, page 4, section 0022, lines 15 and 16. The detection step may involve amplification-based assays and detecting gene copy number, see column 4, lines 12-22; and column 5, lines 56-62. The disclosed method is implemented in conjunction with one or more traditional and well

known anti-cancer therapies, see column 9, line 57-column 10, line 4; and column 10, lines 25-37.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 6,110,690 (issued August 29, 2000), and further in view of U.S. Patent number 6,372,444 (issued April 16, 2002). U.S. Patent #6,110,690 teaches sequence 1, which is the same as Applicants' polynucleotide that encodes amino acid sequence, SEQ ID NO: 2 (BAG4), see attached rai database sheet; and pages 61 and 62 of Applicants' specification. The taught molecules are identified as suppressor of death domain (SODD) molecules, otherwise known as BAG4 molecules or silencer of death domains, see specification, page 4, section 0022. Patent '690 teaches nucleic acids, hybridization probes and primers with a wide variety of applications and methods including specifically hybridizing with SODD molecules, as diagnostic nucleic acids to detect the presence of SODD molecules and as diagnostic molecules for high-throughput clinical diagnoses, see abstract; bridging sentence of columns 1 and 2; and column 5, lines 42-53. Patent '690 does not teach a method wherein an increase in the level of the nucleic acid sequence, relative to normal indicates the presence of breast

cancer in a patient. Patent '690 also does not teach the method of detecting breast cancer, wherein the detection steps comprise using an amplification reaction, detecting an increase in copy number within a breast tissue sample and the patient is undergoing a therapeutic regiment to treat breast cancer.

However, U.S. Patent #6,372,444 does teach methods for diagnosing and treating tumors by detecting SODD polynucleotides in a tissue biopsy wherein an elevated level of SODD opposed to a normal/control sample detects presence of cancer cells, see column 8, lines 20-67; and column 9, lines 40-45. The detection step may involve amplification-based assays, gene copy number, see columns 5, lines 56-62. Moreover, patent '444 teaches the disclosed method is implemented in conjunction with one or more traditional and well known anti-cancer therapies, see column 9, line 57-column 10, line 4; and column 10, lines 25-37. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of patent '444 with patent '690 because both patent teach the applicability of SODD molecules in methods of diagnosis, see abstracts, as well as entire body of both patents. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both patents note SODD molecules are involved in cellular signal transduction and transcriptional activation affecting cancer cell growth and progression, see patent '444, columns 1 and 2; and patent '690, abstract. Moreover, both patent discuss the use of SODD molecules for diagnosing and aiding in treatment options.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.

27 July 2007

